### STATE SETTLEMENT AGREEMENT

### I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the State of Michigan ("the State"), Quest Diagnostics Incorporated ("Quest Diagnostics") and Nichols Institute Diagnostics ("NID") (Quest Diagnostics and NID are collectively referred to as "Defendants"). The State and the Defendants are hereinafter collectively referred to as "the Parties".

#### II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

- A At all relevant times, NID, a wholly owned subsidiary of Quest Diagnostics, manufactured, marketed and sold in vitro diagnostic products ("kits") to laboratories located throughout the United States. Among the kits manufactured, marketed and sold by NID were the following: (1) the Advantage Intact PTH and Bio-Intact PTH kits (respectively the "Intact PTH Kit" and the "Bio-Intact PTH Kit"), which were used by laboratories to measure parathyroid hormone ("PTH") levels in blood samples; (2) the Advantage 25 OH-D kit (the "25 OH-D Kit"), which was used by laboratories to measure hydroxyvitamin D levels in blood samples; (3) the Advantage ACTH kit (the "ACTH Kit"), which was used by laboratories to measure adrenocorticotropic hormone ("ACTH") levels in blood samples; and (4) the Advantage DHEA-S Kit (the "DHEA-S Kit"), which was used by laboratories to measure dehydroepiandrosterone sulfate ("DHEA-S") levels in blood samples.
- B. On or about April 9, 2004, Thomas Cantor ("Cantor") filed a qui tam action in the United States District Court for the Eastern District of New York captioned <u>United States of America ex rel. Thomas Cantor</u>, et al., v. Nichols Institute Diagnostics, Inc., et al., Civil Action

No. 04-1494, in which he alleged that the Intact PTH Kit and Bio-Intact PTH Kits provided falsely elevated results (hereinafter referred to as the "Civil Action").

- C. NID has agreed to enter into a plea agreement with the United States Attorney for the Eastern District of New York; if the Plea Agreement is approved by the court, NID will plead guilty pursuant to Fed. R. Crim. P. 11, to specific conduct further described in an Information to be filed in <u>United States v. Nichols Institute Diagnostics</u> (the "Federal Criminal Action"). Quest Diagnostics has agreed to enter into a non-prosecution agreement with the United States Attorney for the Eastern District of New York.
- D The Defendants have agreed to enter into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States (as that term is defined in the Federal Settlement Agreement).
- E. The State contends that the Defendants submitted or caused to be submitted claims for payment to the State's Medicaid Program, 42 U.S.C. §§ 1396-1396(v) ("Medicaid Program")
- F The State contends that it has certain civil and administrative causes of action, as specified immediately below, against the Defendants for knowingly submitting or causing false and/or fraudulent claims to be submitted to the State's Medicaid Program:
  - (1) Between May 1, 2000 through April 30, 2006, NID manufactured, marketed and sold the Intact and Bio-Intact PTH Kits despite knowing that some kits produced results that were materially inaccurate and unreliable, thereby causing some clinical laboratories that purchased and used the Intact and Bio-Intact PTH Kits to submit false claims for reimbursement to the Medicaid Program; and,

- (2) For various periods of time between the following dates, NID also manufactured, marketed and sold the following kits, some of which produced results that were materially inaccurate and unreliable, thereby causing some clinical laboratories that purchased and used these kits for testing to submit false claims for reimbursement to the Medicaid Program:
  - (a) Between May 1, 2000 and May 31, 2005, the ACTH Kit;
  - (b) Between April 1, 2002 and April 30, 2006, the 25-OH-D Kit; and,
- (c) Between September 1, 2002 and November 30, 2005, the DHEA-S Kit. (this along with paragraphs B and E "the Covered Conduct").
- G. Quest voluntarily closed NID in April 2006.
- H. This Agreement is neither an admission of facts or liability by Defendants nor a concession by the State that its claims are not well founded. Except for the specific conduct for which NID is pleading guilty, as described in the Plea Agreement filed in the Federal Criminal Action, Defendants expressly deny the allegations of the State as set forth herein and in the Civil Action and deny that they have engaged in any wrongful conduct in connection with the Covered Conduct. Neither this Agreement, its execution nor the performance of any obligation under it, including any payment, nor the fact of the settlement, is intended to be or shall be understood as, an admission of liability or wrongdoing, or other expressions reflecting on the merits of the dispute by Defendants.
- I To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these causes of action, the Parties mutually desire to reach a full and final settlement as set forth below

### III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

- 1. a. Pursuant to the separate Federal Settlement Agreement, Defendants agree to pay to the United States the sum of Two Hundred Sixty-Two Million Dollars (\$262,000,000 00) plus 3 875% annual interest on that amount accruing between October 1, 2008 and the Effective Date of the Federal Agreement (the "Federal Settlement Amount"), which includes the federal portion of the settlement allocated to Medicaid Program The total Medicaid settlement amount, including federal and state share, is Twelve Million Four Hundred Thousand dollars (\$12,400,000 00) (the "Settlement Amount") Pursuant to the terms of Paragraph III.1 b infra, Defendants agree to pay to all of the Medicaid Participating States and the District of Columbia (which shall be defined, for purposes of this Agreement, as a State) the sum of Six Million Two Hundred Thousand dollars (\$6,200,000 00) plus 3 876% annual interest on that amount accruing between the Effective Date of the Federal Settlement Agreement and the date on which the State's share of the Medicaid State Settlement Amount (defined below) is paid to the State. The amount Six Million Two Hundred Thousand dollars (\$6,200,000 00), plus accrued interest shall be defined as the "Medicaid State Settlement Amount"
- b Payment of the Medicaid State Settlement Amount shall be made to the Medicaid Participating States no later than seven (7) business days after Defendants receive written payment instructions from the National Association of Medicaid Fraud Control Units State Settlement Team (the "NAMFCU Team") and following the earliest of the dates on which the following occurs:

- (i) the individual Medicaid State Settlement Agreements from the Medicaid Participating States are fully executed and delivered to Defendants' counsel, or
- (ii) as otherwise agreed in writing by Defendants' counsel and the NAMFCU team.
- c. If neither condition is satisfied within 90 days subsequent to the Effective Date of the Federal Settlement Agreement, defendants' offer to resolve this matter with the individual Medicaid Participating States shall become null and void absent written agreement between Defendants' counsel and the NAMFCU team to extend the 90 day period.
- d The total portion of the Settlement Amount paid by Defendants in settlement for the Covered Conduct to the State is \$ 60,567 69, consisting of a portion paid to the State under this Agreement and another portion paid to the Federal Government as part of the Federal Settlement Agreement. The individual portion of the Medicaid State Settlement Amount allocated to the State under this Agreement is the sum of \$ 25,096 65, plus applicable interest.
- Contingent upon the receipt of their appropriate portion of the Medicaid State Settlement Amount, the Medicaid Participating States agree to pay, as soon as feasible after such receipt, agreed-upon amounts that have been addressed in side letters to the Plaintiff-Relators in the Civil Action
- The State agrees to dismiss with prejudice any claims pendant to the Civil Action or relating to Defendants' participation in the Covered Conduct, including any qui tam "whistleblower" claims, in which the State has intervened and/or has the authority to dismiss, currently pending or filed in the future against Defendants in State or Federal courts.
- 4. Subject to the exceptions in Paragraphs 5 and 12 below, and in consideration of the obligations of Defendants set forth in this Agreement, conditioned upon receipt by the State

of its share of the Medicaid State Settlement Amount, the State (on behalf of itself, its officers, agents, agencies, political subdivisions, employees, servants and departments) agrees to release Defendants, and each of their current and former United States-based parent corporations, predecessors, affiliates, brother or sister corporations, divisions, direct or indirect subsidiaries, successors, transferees, heirs, and assigns, and joint ventures and their current and former owners, directors, officers, attorneys, employees, shareholders, joint venturers, agents and successors and assigns of any of them, individually and collectively (collectively, the "Released Entities") from any civil or administrative monetary cause of action that the State has or may have for any claims submitted or caused to be submitted to the State Medicaid Program for the Covered Conduct

5. Notwithstanding any term of this Agreement, the State specifically does not release any person or entity from any of the following liabilities: (a) any criminal, civil, or administrative liability arising under state revenue codes; (b) any criminal liability not specifically released by this Agreement; (c) any civil liability that Defendants have or may have under any state statute, regulation, or rule not covered by this Agreement; (d) any liability to the State for any conduct other than the Covered Conduct; (e) any liability that may be asserted by private payors or insurers for claims paid by the State's Medicaid program on a capitated basis; (f) any liability based upon obligations created by this Agreement; (g) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from the State's Medicaid program; (h) any express or implied warranty claims or other claims for defective or deficient products and services provided by Defendants; (i) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or (j) any liability based on a failure to deliver items or services due

- This Agreement is expressly conditioned upon resolution of the Federal Criminal Action. In consideration of the acceptance of NID's plea of guilty in the Federal Criminal Action, and Quest Diagnostics' execution of the Non-Prosecution Agreement, the State's Medicaid Fraud Control Unit ("MFCU") agrees that it shall not further criminally investigate, prosecute, or refer for prosecution or criminal investigation to any agency, Quest Diagnostics, NID, or their present and former parents, divisions, and subsidiaries and their predecessors, successors and assigns, for the Covered Conduct
- 7. In consideration of the obligations of Defendants set forth in this Agreement, and the Corporate Integrity Agreement ("CIA") Quest Diagnostics will enter into with the Office of the Inspector General of the United States Department of Health and Human Services ("HHS-OIG") in connection with this matter, and conditioned on receipt by the State of its share of the State Medicaid Settlement Amount, except as reserved in Paragraph 5 above and subject to Paragraph 12 below, the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid program against the Released Entities for the Covered Conduct, the allegations in the Civil Action, the Federal Settlement Agreement, Quest Diagnostics' Non-Prosecution Agreement with the United States or NID's conviction in the Federal Criminal Action. Nothing in this Agreement precludes the State from taking action against Defendants in the event that Defendants are excluded by the federal government, or for conduct and practices other than the Covered Conduct, the allegations in the Civil Action, the Federal Settlement Agreement, Quest Diagnostics' Non-Prosecution Agreement with the United States or NID's conviction in the Federal Criminal Action.

- The Released Entities waive and shall not assert any defenses they may have to criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the United States' Constitution or the Excessive Fines Clause of the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action
- 9. In consideration of the obligations of the State set forth in this Agreement, the Released Entities waive and discharge the State, its agencies, political subdivisions, officers, agencies, departments, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which the Defendants have asserted, could have asserted, or may assert in the future against the State, its agencies, political subdivisions, officers, agencies, departments, employees, servants, and agents, arising from the State's investigation and prosecution of the Covered Conduct
- The amount that Defendants must pay to the State pursuant to Paragraph 1 above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the State's Medicaid program, or any other state payor, for the Covered Conduct; and, if applicable, Defendants agree not to resubmit to the State's Medicaid program or any other state payor, any previously denied claims, which denials were based on the Covered Conduct, and agree not to appeal or cause the appeal of any such denials of claims.
- Defendants shall not seek payment for any of the claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

- Defendants expressly warrant that they have reviewed their respective financial condition and are currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment of the Federal Settlement Amount and the Medicaid State Settlement Amount as set out in paragraph I herein. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Defendants within the meaning of 11 U.S.C. § 547(c)(1), and (b) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange. The Parties further warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay or defraud any entity to which Defendants were or became indebted to, on or after the date of this transfer, within the meaning of 11 U.S.C. §548(a)(1).
- 13. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 14. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties and Released Entities only, and by this instrument the Parties do not release any liability against any other person or entity.

- Nothing in this Agreement constitutes an agreement by the State or Defendants concerning the characterization of the amounts paid hereunder for purposes of the Federal or State's revenue code.
- In addition to all other payments and responsibilities under this Agreement,

  Defendants agree to pay all reasonable travel costs and expenses of the NAMFCU Team

  Defendants will pay this amount by separate check made payable to the National Association of Medicaid Fraud Control Units after the Medicaid Participating States execute their respective Agreements or as otherwise agreed by the Parties
  - 18. This Agreement is governed by the laws of the State.
- 19. The undersigned Defendant signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.
- 20. The "Effective Date" of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement
- This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.
- This Settlement Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

- 23. This Agreement may be executed in counterparts, each of which shall constitute an original, and all of which shall constitute one and the same Agreement.
- Notwithstanding any other provision of this Agreement, if the guilty plea referred to in Paragraph C of the Preamble is withdrawn or not accepted by the Court, this Agreement shall be null and void at the option of either the State or Defendants. If either Party exercises this option, by notifying all Parties through counsel within 3 business days of the withdrawal of the Plea or the Court's rejection of the plea, the Parties agree that the Agreement is rescinded. If the Agreement is rescinded, Defendants waive all affirmative defenses based in whole or in part on the running of the Statute of Limitations during the period of time from the Effective Date of the Agreement through the date on which the Agreement was rescinded.

## STATE OF MICHIGAN

By:	[Name] Elizabeth Valentine [Title] Assistant Attorney General, Health Care Frand Division OFFICE OF THE ATTORNEY GENERAL
Ву:	James R. Brandell Dated: 5/19/2009  [National Director, Beneficial Program: Ways consent & Manufacture Sources.

## **DEFENDANT COMPANIES**

Ву:	Name: Michael E. Prevoznik  Title: Senior Vice President and General Counsel  Quest Diagnostics Incorporated	Dated:	7/28/09
Ву:	Name: Title:	Dated: _	·
Ву:	Name: Hope S. Foster Counsel to Quest Diagnostics Incorporated and Nich	Dated: _	813 09  Ite Diagnostics

## **DISTRIBUTION OF PROCEEDS**

## Quest Diagnostics, Inc./Nichols Institute Diagnostics

# State of Michigan

тот	AL MEDICAID SETTLEMENT (STATE/FEDERAL)	\$60,567.69
1.	State Share of Medicaid Restitution	\$25,096.65
2	State Share of Additional Recoveries	\$1,398.63
3.	Interest	\$300.28
4	Total State Settlement Amount	\$26,795.57*

# \*THESE ARE STATE MONIES ONLY; DO NOT SEND OR CREDIT ANY AMOUNT TO THE FEDERAL GOVERNMENT.

IF ANY MECU STATES HAVE QUESTIONS ON HOW TO REPORT THESE MONIES, PLEASE DIRECT QUESTIONS TO:

Sharon Colby, Director Medicaid Fraud Unit Oversight Staff Office of the Inspector General

202-260-3711